FH [redacted]

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[redacted]

DECISION

MPA/161993

PRELIMINARY RECITALS

Pursuant to a petition filed November 17, 2014, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on January 08, 2015, at Kenosha, Wisconsin.

The issue for determination is whether the Department of Health Services, Division of Health Care Access and Accountability (DHS) correctly denied coverage of an RT300 Functional Electrical Stimulator.

NOTE: the record was held open until January 9, 2015, to give Petitioner an opportunity to supplement the record. Petitioner's physical therapist submitted an FDA listing and a Research Article concerning body composition. They have been marked as Exhibits 6 and 7 respectively. The provider of the RT300 submitted an FDA Clearance and an electronic folder of six journal articles. They have been marked as Exhibits 4 and 5 and entered into the record.

With Petitioner's permission Exhibits 4 through 7 were submitted to [redacted], DHS's physician consultant for review. She submitted a response dated January 21, 2015, which has been marked as Exhibit 8 and entered into the record.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:
Petitioner:

[redacted]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703
By: OIG by letter
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272

P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:
Mayumi M. Ishii
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES # [redacted]) is a resident of Kenosha County.

2. Petitioner is currently 22 years old. He suffered a spinal cord injury and is diagnosed with C6 tetraplegia per American Spinal Injury Association [ASIA] standards. (Letter of Medical Necessity; Exhibit 3, pg. 74)

3. Petitioner has no use of his legs and has limited use of his arms. He is able to bend his elbows and wrists, but cannot use his hands. (Testimony of Petitioner and Exhibit 3, pg. 69)

4. On October 14, 2014, Restorative Therapies, on behalf of the Petitioner, submitted a prior authorization request for an RT300 Functional Electrical Stimulator at a cost of $16,900.00. (Prior Authorization Request Form; Exhibit 3, pg. 69)

5. Restorative Therapies used a service code of E1399, which is a code used for miscellaneous durable medical equipment. (Id.)[1]

6. The RT 300 Functional Electrical Stimulator[2] (RT300) is a motorized cycle that allows paralyzed individuals to cycle, by connecting paralyzed limbs to the cycle with electrodes. (Exhibit 3, pgs. 90-91; Exhibit 4)

7. According to the 510(k) Summary that Restorative Therapies submitted to the Food and Drug Administration (FDA), the RT300 is intended for "general rehabilitation for: 1. Relaxation of muscle spasms 2. Prevention or retardation of disuse atrophy 3. Increasing local blood circulation 4. Maintaining or increasing range of motion". (Exhibit 4)

8. The FDA determined that the RT300 did not need a premarket approval application (PMA), because it was at least as safe and effective as another legally marketed device, and it has given Restorative Therapies permission to market the RT300.[3]

9. Petitioner intends to use the RT300 to maintain range of motion, reduce spasticity and prevent muscle atrophy in his legs. (Testimony of [redacted], Petitioner's physical therapist; Exhibit 1, pgs. 35-36)

10. Petitioner previously used the RT 300 while in an in-patient setting at Froedert Hospital and again, in an outpatient setting while receiving therapy at Shepherd Center. Petitioner engaged in

[1] See page 13 of the DME Index. A link to the index may be found at:

https://www.forwardhealth.wi.gov/WIPortal/Tab/42/icscontent/Provider/medicaid/MedicalEquipmentVendor/resources_25.htm.spage

[2] Functional Electric Stimulator or FES ergometers should not be confused with passive range of motion devices, which do not stimulate the patient's muscles to push the pedals of the cycle and are intended for used after surgery. See Exhibit 3, pg. 90-91; See also: http://www.arthroscopy.com/sp06001.htm

[3] See http://www.accessdata.fda.gov/cdrh_docs/pdf9/k090750.pdf ; See also 21 CFR §807.92(a)(3) And http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

15 sessions between September 27, 2013 and February 4, 2014. (Testimony of Petitioner; Exhibit 1, pg. 60)

11. Petitioner anecdotally noted a decrease in spasticity, which corresponded to a decreased need for pain medication. (Testimony of Petitioner)

12. On October 27, 2014, the Department of Health Services (DHS) sent the Petitioner and Restorative Therapies notices advising them that the request for the RT300 was denied. (Exhibit 3, pgs. 105-110)

13. The Petitioner filed a request for fair hearing that was received by the Division of Hearings and Appeals on November 17, 2014. (Exhibit 1)

DISCUSSION

In the case at hand, the Petitioner seeks coverage of the RT300, a piece of durable medical equipment.

Wis. Admin. Code DHS §101.03(5) defines "durable medical equipment" as, "equipment which can withstand repeated use, is primarily used for medical purposes, is generally not useful to a person in the absence of illness or injury and is appropriate for use in the home."

Per Wis. Admin. Code DHS §107.24(3)(a), items listed in the Wisconsin Durable Medical Equipment (DME) and medical supplies indices as needing prior authorization, must in fact, go through the prior authorization process. According to page 13 of the DME Index, purchases of miscellaneous medical equipment, like the RT300, that are coded E1399 must receive prior authorization for coverage.

Petitioner has the burden to prove, by a preponderance of the credible evidence, that his request for prior authorization of an RT300 meets the approval criteria. Gonwa v. Department of Health and Family Services, 2003 WI App 152, 265 Wis.2d 913, 668 N.W.2d 122 (Ct.App.2003)

Does the RT300 fall into one of the categories of durable medical equipment covered by Medical Assistance?

Wis. Admin. Code DHS §107.24(2)(c) lists the categories of durable medical equipment that are covered by Wisconsin's Medical Assistance (MA) programs:

> **(c)** *Categories of durable medical equipment.* The following are categories of durable medical equipment covered by MA
>
> 1. Occupational therapy assistive or adaptive equipment. This is medical equipment used in a recipient's home to assist a disabled person to adapt to the environment or achieve independence in performing daily personal functions. Examples are adaptive hygiene equipment, adaptive positioning equipment and adaptive eating utensils.
>
> 2. Orthopedic or corrective shoes. These are any shoes attached to a brace for prosthesis; mismatched shoes involving a difference of a full size or more; or shoes that are modified to take into account discrepancy in limb length or a rigid foot deformation. Arch supports are not considered a brace. Examples of orthopedic or corrective shoes are supinator and pronator shoes, surgical shoes for braces, and custom-molded shoes.

3. Orthoses. These are devices which limit or assist motion of any segment of the human body. They are designed to stabilize a weakened part or correct a structural problem. Examples are arm braces and leg braces.

4. Other home health care durable medical equipment. This is medical equipment used in a recipient's home to increase the independence of a disabled person or modify certain disabling conditions. Examples are patient lifts, hospital beds and traction equipment.

5. Oxygen therapy equipment. This is medical equipment used in a recipient's home for the administration of oxygen or medical formulas or to assist with respiratory functions. Examples are a nebulizer, a respirator and a liquid oxygen system.

6. Physical therapy splinting or adaptive equipment. This is medical equipment used in a recipient's home to assist a disabled person to achieve independence in performing daily activities. Examples are splints and positioning equipment.

7. Prostheses. These are devices which replace all or part of a body organ to prevent or correct a physical disability or malfunction. Examples are artificial arms, artificial legs and hearing aids.

8. Wheelchairs. These are chairs mounted on wheels usually specially designed to accommodate individual disabilities and provide mobility. Examples are a standard weight wheelchair, a lightweight wheelchair and an electrically-powered wheelchair.

The RT300 clearly does not fall under categories, 2, 3, 5, 7 or 8 of covered durable medical equipment, because it is not an orthopedic / corrective shoe; it is not an orthose; it is not oxygen therapy equipment; it is not a prosthetic and it is not a wheelchair. The RT300 is essentially a piece of physical therapy equipment used to manipulate a patient's legs to maintain range of motion, decrease spasticity and decrease muscle atrophy. However, it does not fit under categories 1 and 6, adaptive equipment for occupational therapy or physical therapy, since it is not intended to help the Petitioner become more independent in performing activities of daily living, such as eating or moving about his home safely.

The remaining question is whether RT300 fits under category 4, "other home health care durable medical equipment". Such equipment is defined as, "medical equipment used in a recipient's home to increase the independence of a disabled person or modify certain disabling conditions". Wis. Admin. Code DHS §107.24(2)(c) *Supra.*

As previously discussed there is nothing in the record suggesting that the RT300 is intended to help the Petitioner become more independent with a specific task, such as eating, dressing, walking, grooming, etc., so it does not qualify as other home healthcare equipment used to increase the independence of a disabled person.

Neither the administrative rules, nor the on-line provider handbook make clear what is meant by "other home health care durable equipment used to modify certain disabling conditions". Indeed, the examples listed were not helpful.[4]

[4] See the topic #1746 in the on-line provider handbook located at: https://www.forwardhealth.wi.gov/WIPortal .

According to the on-line provider handbook, "Examples of home health equipment are hospital beds, adaptive hygiene equipment, food pumps, glucose monitors, adaptive positioning equipment and adaptive eating utensils." The administrative rule, also lists traction devices as an acceptable example of other home health equipment. All the devices listed help an individual complete a specific task such as breathing, positioning, transfers, getting nutrition, etc. However, it is not clear how any of these pieces of equipment "modify a disabling condition".

The plain language meaning of "modify" is to change something, or makes less severe. *The American Heritage Dictionary 884 (New College Edition 1976)* It can reasonably be concluded that a disabling condition would be something like the Petitioner's spinal cord injury and resulting paralysis.

There is no evidence and no claim that the RT300 can heal or reduce the severity of a spinal cord injury nor is there any claim that the RT300 can reverse or mitigate paralysis. On the contrary, in his request for hearing, the Petitioner states, "The RT300 has NOT been prescribed to provide ambulation…" As such, the RT300 is not equipment used in the home to modify a disabling condition.

Based upon all of the foregoing, it is found that the RT300 does not fall into any of the categories of durable medical equipment that is covered by Medical Assistance, pursuant to Wis. Admin. Code DHS §107.24(2)(c).

The RT300 does not meet the definition of Medical Necessity

Even if the RT300 did fall under category 4, "other home health care durable medical equipment", it would not meet the definition of medically necessary under Wis. Adm. Code. §DHS 101.03(96m)

"Medically necessary" means a medical assistance service under ch. DHS 107 that is:

(a) Required to prevent, identify or treat a recipient's illness, injury or disability; and
(b) Meets the following standards:
1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
3. Is appropriate with regard to generally accepted standards of medical practice;
4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
5. Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;
6. Is not duplicative with respect to other services being provided to the recipient;
7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and
9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.

Wis. Adm. Code. §DHS 101.03(96m)

DHS contends that the RT300 does not meet the legal definition of medically necessary because it has not been proven to have medical value or usefulness.

Restorative Therapies argues that the RT300 has been proven safe and effective for its intended uses, because it was given market clearance by the FDA.

It is true that the FDA gave Restorative Therapies permission to sell the RT300 as a device for 1. Relaxation of muscle spasms, 2. Prevention or retardation of disuse atrophy, 3. Increasing local blood circulation, and 4. Maintaining or increasing range of motion. Permission was granted because the RT300 was determined to be similar enough to another device that was already marketed for the same purposes and that was found to be safe and effective. (Exhibit 4) So, one might conclude that the device has already established its usefulness.

However, the clearance was based upon a report in which Restorative Therapies concluded that its equipment was similar enough to a previously marketed device that was determined to be safe and effective. The clearance does not appear to be based upon an independent review of the product. It is curious that even though Restorative Therapies claims to have hundreds of studies proving the effectiveness of the RT300 to reduce spasticity, prevent atrophy, increase blood circulation, and maintain range of motion, it did not produce a single study that conclusively stated that use of the RT300 or FES devices does, in fact, maintain range of motion, decrease spasticity and decrease muscle atrophy in tetraplegic patients, like the Petitioner.

[redacted], in her consultant letter, opined that there have not been sufficient, good quality studies that support the claim that the RT300 can reduce spasticity, prevent atrophy, increase blood circulation or maintain range of motion. The absence of any good quality studies in the record and the Hayes Report, which evaluated existing studies of FES equipment like the RT300, support [redacted]'s opinion that the research concerning use of the RT300 is promising, but is not sufficient to prove the claimed medical value.

I note that the Petitioner testified that his spasticity decreased so much that he did not need as much pain medication. While I do not doubt the sincerity of Petitioner's testimony, the medical records provided for the hearing do not corroborate his claim. Further, the report submitted by Petitioner's physical therapist did not contain any quantitative information about any measurable gains Petitioner made while using the RT300. (See Exhibit 1, pgs. 35-36) The report from [redacted], the physical therapist employed by Restorative Therapies, also lacks specific, measurable, quantitative information regarding Petitioner's range of motion, spasticity, muscle mass, or cardiovascular health.

Based upon all of the foregoing, it is found that the record has not shown the RT300 to be of proven medical value or usefulness. As such, it does not meet the legal definition of medical necessity under Wis. Adm. Code. §DHS 101.03(96m) and cannot be covered by Medical Assistance. (See also Wis. Admin. Code 107.24(5)(e) *non-covered services*: "Items which are not generally accepted by the medical profession as being therapeutically effective…"

CONCLUSIONS OF LAW

DHS correctly denied coverage of an RT300 Functional Electrical Stimulator.

THEREFORE, it is **ORDERED**

That the petition is dismissed

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision.** Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Milwaukee, Wisconsin, this 23rd day of February, 2015.

\sMayumi M. Ishii
Administrative Law Judge
Division of Hearings and Appeals

State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on February 23, 2015.

Division of Health Care Access and Accountability